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(51) INT CL<sup>5</sup>

**A61M 16/06**

(52) UK CL (Edition M )

**A5T TCH TCT**

(56) Documents Cited

**GB 2062477 A GB 0889130 A EP 0085639 A1**  
**WO 93/01854 A1 US 4896666 A US 3809079 A**

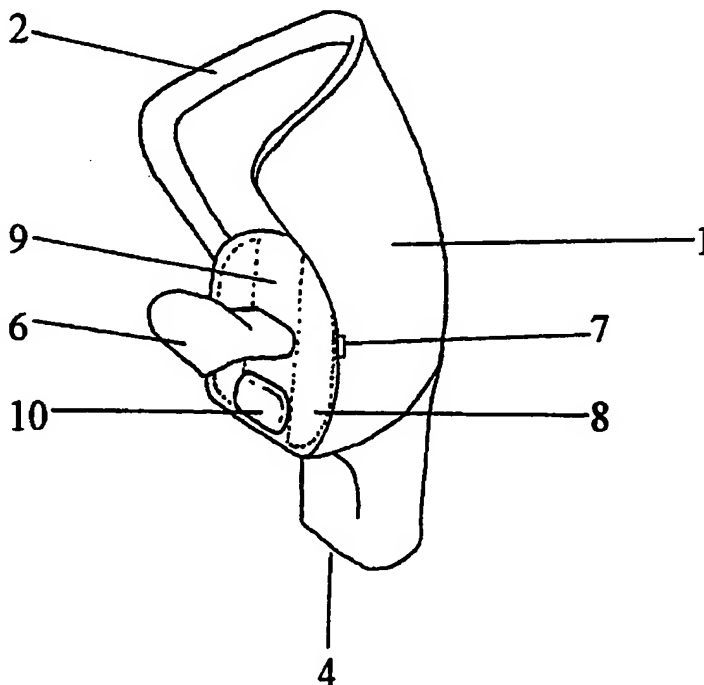
(58) Field of Search

**UK CL (Edition M ) A5T TCA TCH TCKA TCL TCT**  
**INT CL<sup>5</sup> A61M 16/00 16/06 , A62B 18/02**  
**ONLINE DATABASE : WPI**

(54) **A self-retaining device to facilitate the inhalation of gas to human beings and animals**

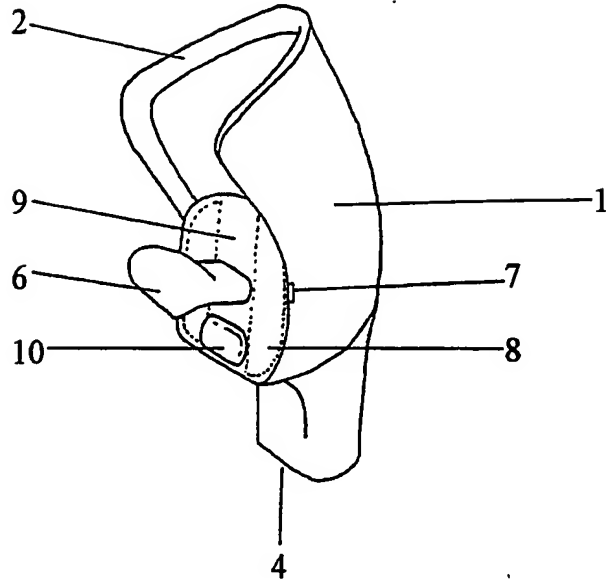
(57) A device for the delivery of gas including anaesthetic vapours particularly to children comprises a teat (6), body (1) and seal (2) closely applied to the face, sealing without excessive pressure around the nose to prevent the escape of gases towards the eyes. The seal may encircle the oral as well as nasal airway. The mask is largely retained by the child although straps may be provided. Due to the progressive change in the morphology of the face during the first 4 years of life, a range of masks is necessary to ensure an adequate seal. A port and connectors are provided to allow connection to all types of gas delivery tubing or monitoring equipment. An oropharyngeal airway may be substituted for the teat.

**Fig 1**

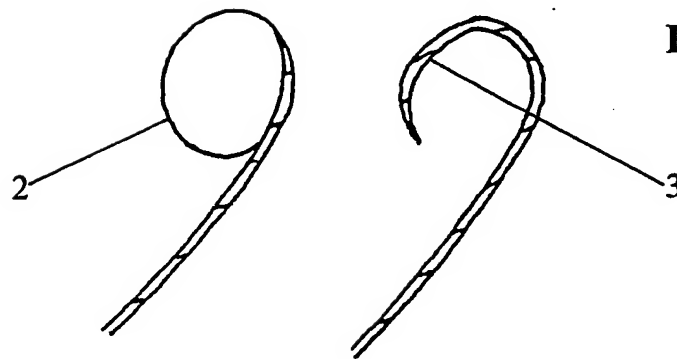


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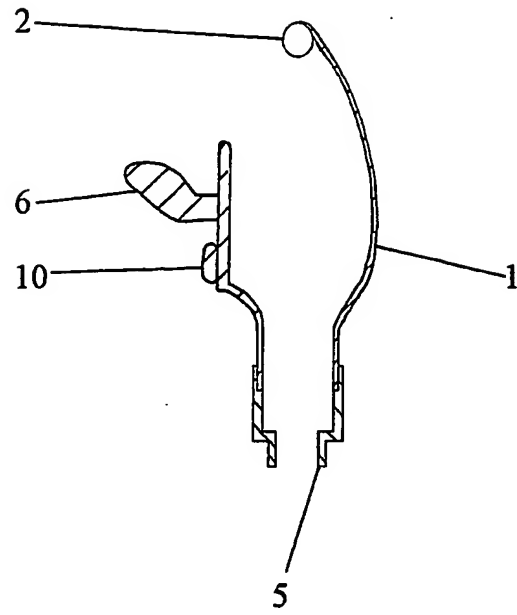
**Fig 1**



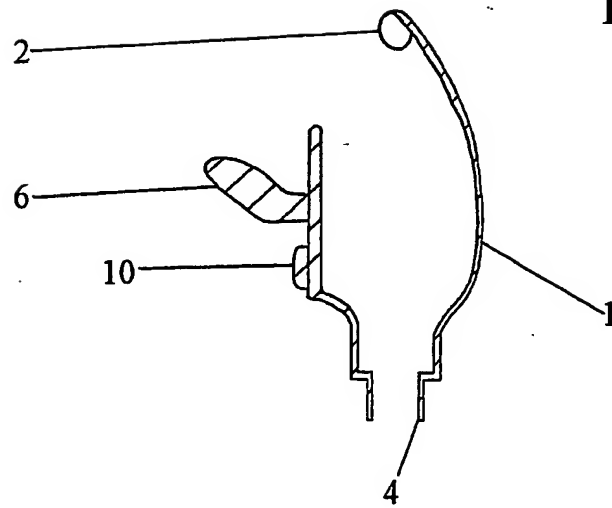
**Fig 2**



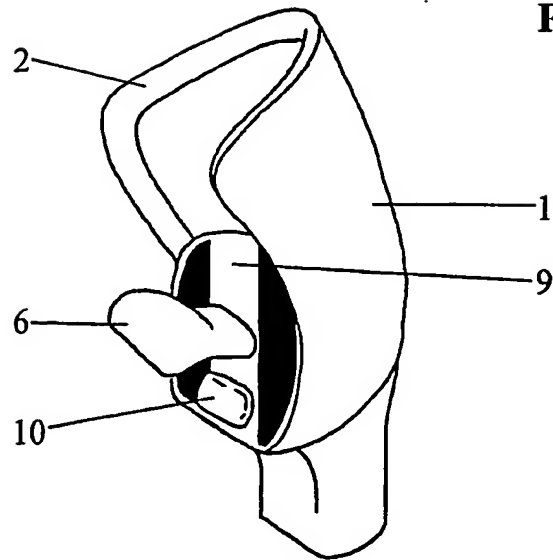
**Fig 3**



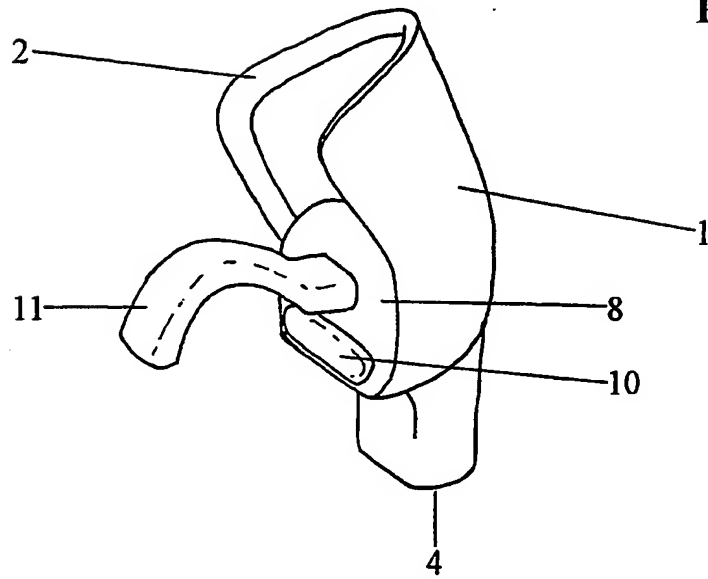
**Fig 4**



**Fig 5**



**Fig 6**



## **A SELF - RETAINING DEVICE TO FACILITATE THE INHALATION OF GAS TO HUMAN BEINGS AND ANIMALS**

This invention relates to a device for the delivery of gases and vapours to breathing organisms

### **BACKGROUND**

The human mid face changes shape tremendously over the first few years of life which, in conjunction with human behaviour over this time period has made the delivery of gasses such as oxygen difficult. The usual practice at present with small babies is to use a box large enough to enclose the babies' head, a smaller version of the old oxygen tent. Oxygen is then fed into the box at the relevant concentration for the child to breath. When the child will no longer tolerate this, usually when the child achieves the ability to move independently, a mask fitting over most of the lower face from around the bridge of the nose to around the chin is used. This allows better access to the patient but is poorly tolerated by the majority of patients, often spending more time off the face than on. The last alternative is a nasal cannula (either a thin tube pushed a couple of centimetres up the nose or a tube running across the upper lip with prongs inserted into the nose are used). However these are often removed by the patient and it is also impossible to regulate the concentration of oxygen delivered to the patient. The commonest attempt to keep the tubing in place is to stick it to the childs' face with adhesive tape, with all the attendant risks of damage to the childs' delicate skin. None of the present systems are without fault and are unacceptable to the majority of patients in this age group to greater or lesser degree. This problem and the solution offered is applicable to other species of breathing organisms.

The design of mask contained herein is one based around the fact that when unwell or frightened the majority of children in the age range considered (0-4 years) find comfort in and often demand, the nipple. The design is therefore inherently more acceptable to the patient. Also the design avoids the area near the childs eyes, thus being less threatening when in place. The younger the child the more acceptable the device will be, indeed below the age of three months babies are obliged to retain the teat because of the suckling reflex, consequently they are also obligate nose breathers. These reflexes will retain the teat even during sleep. Thus the present need for the headbox with its attendant difficulties of access to the child and problems of maintaining gas delivery when handling the baby are avoided.

Induction of general anaesthesia in small children using volatile agents rather than the intravenous route necessitates the masks used currently to be forcibly held against the child's face. A variety of toys have been made such as the telephone with the gas coming out of the mouthpiece. However they all require the child to "play the game" and the majority of the gas is delivered to the room and not the child, with the inherent risks to attendant personnel. As the child will understandably be somewhat apprehensive about their predicament, the design described will be given to the child before reaching the operating theatre as a soother and would then only require connecting to the gas supply during which time the child retains the mask in position.

In some circumstances where the child's airway is compromised, such as during recovery from general anaesthesia or a convulsion, an oropharyngeal airway may substitute for the nipple thus ensuring adequate delivery of gas to the patient.

**This invention** provides a self retaining device to facilitate the inhalation of gas to human beings and animals. It comprises a teat, body and seal with means for entry and exit of gases.

For the most part the mask is self-retaining, however there is the provision for a strap to allow support of the mask in place in case of unusual circumstances such as unpredictable aggressive behaviour or temper tantrums in the older age range, or episodes of tongue thrusting in the younger age group. It is also possible that whilst the teat may provide comfort, and therefore wish to be retained by the child, they are too weak to do so.

There is a seal that fits snugly against the nose and mid face comprising a thin low pressure gas filled tube, or a soft, rolled edge. The gas flow enters at the lower aspect of the body of the mask.

At the lower aspect there will be a port that will accept a variety of adapters which will enable the fitting of differing types of connectors. These adapters can be considered an integral part of the design. Some models may have the adapter as an integral part of the mask for users only requiring one connection and the minimum of dead space.

As the relationship of the nose to the mouth changes over the relevant age range, a range of masks will be necessary to ensure an accurate seal. This range will not simply be of increasing size, but of differing profiles matching the changes in the growing child's face.

In some circumstances, gas flow to the child's mouth may be required when mixed nose and mouth breathing occurs. To facilitate this the plate at the base of the teat is removable allowing free flow of gas.

In some circumstances where the patient is unable to protect their own airway, an oropharyngeal airway will substitute for the teat. This will be of use to all ages.

Different species will require their own range of masks.

**A specific embodiment of the invention will now be described by way of example with reference to the accompanying drawing in which:-**

**Figure 1 shows the mask in perspective**

**Figure 2 illustrates the two types of seal**

**Figure 3 demonstrates the port and one of the connectors**

**Figure 4 shows one of the integrated models.**

**Figure 5 demonstrates the mask with the teat base plate removed to allow gas flow to the mouth.**

**Figure 6 demonstrates the mask incorporating an oropharyngeal airway**

**Referring to the drawing, the mask comprises a body (1) with a soft conforming seal (2 and 3) at its upper part allowing close application to the nose and mid face above the mouth. The lower aspect forms the port of entry and exit for gases(4 and 5). The lower portion is in continuity with a teat (6) which will be retained within the child's mouth. The connection of the mask to the gas supply is effected through the port either directly(4) or via a connector (5). Points of attachment are provided to allow the support of the mask with straps if required (7). The nipple base plate (8) is removably attached to the nipple support bar (9) upon which is a buffer pad (10). In the models incorporating an oropharyngeal airway (11) this will replace the teat as shown.**

## **CLAIMS**

1. A self retaining device to facilitate the inhalation of gas to human beings and animals. It comprises a teat, body and seal with means for entry and exit of gases.
2. A device as claimed in claim 1 wherein the body of the mask closely follows the profile of the face enabling a satisfactory seal without excessive pressure.
3. A device as claimed in Claim 1 or claim 2 wherein connections are provided in order to attach straps to support the mask on the face.
4. A device as claimed in Claim 1 or Claim 2 or claim 3 wherein the seal comprises a thin low pressure gas filled tube.
5. A device as claimed in Claim 1 or Claim 2 or claim 3 wherein the seal consists of a soft pliable rolled edge.
6. A device as claimed in Claim 4 or Claim 5 wherein the mask has as part of the body a connector enabling attachment to gas tubing or a gas tubing connector.
7. A device as claimed in Claim 4 or Claim 5 wherein a port within the lower portion of the body of the mask enables a variety of connectors to be attached to facilitate the connection of various different gas supply tubing or monitoring equipment.
8. A device as claimed in Claim 6 or Claim 7 where the nipple base plate is releasably attached to the mask to allow for the obstruction or free flow of gas to the mouth.
9. A device as claimed in any preceding claim in which the teat is replaced by an oropharyngeal airway.
10. A device as claimed in any preceding claim in which the seal encircles the edge of the body creating a chamber surrounding the nasal and oral airway.
11. A device substantially described herein with reference to figures 1-6 of the accompanying drawings.



**Patents Act 1977**  
**Examiner's report to the Comptroller under Section 17**  
**(The Search report)**

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**Relevant Technical Fields**

- (i) UK Cl (Ed.M)     AST (TCA, TCH, TCKA, TCL,TCT)  
(ii) Int Cl (Ed.5)     A61M 16/00, 16/06 A62B 18/02

Search Examiner  
L V THOMAS

Date of completion of Search  
18 JULY 1994

**Databases (see below)**

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

Documents considered relevant following a search in respect of Claims :-  
1-11

(ii) ONLINE DATABASE: WPI

**Categories of documents**

- X: Document indicating lack of novelty or of inventive step.     P: Document published on or after the declared priority date but before the filing date of the present application.
- Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.     E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.
- A: Document indicating technological background and/or state of the art.     &: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 2062477 A	(BRUNSWICK Mfg) see lines 58-100 page 1 and lines 17-97 page 2	2, 4, 6, 7, 9, 10
X	GB 889130	(AMALGAMATED DENTAL CO) see whole document	2, 6, 9, 10
X	EP 0085639 A1	(DE GREEF et al) see lines 1-16 page 2 and lines 3-8 page 5	1,6
X	WO 93/01854 A1	(DAHLSTRAND) see line 22 page 2 - line 4 page 3 and figures	1, 2, 6, 10
X	US 4896666	(HINKLE) see line 4 column 3 - line 61 column 4	1, 2, 6, 8, 10
X	US 3809079	(BUTTARAVOLI) see lines 44-50 column 1 and lines 11-61 column 2	2, 5, 6, 9, 10

**Databases:** The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).